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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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09/138,091 08/21/98 ADAMS

EXAMINER 9491-013-27

024510 HM12/1023  
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ART UNIT PAPER NUMBER  
SPECTOR, L 22

1647  
DATE MAILED:

10/23/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/6/01  
☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

☒ Claim(s) 46-57 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 49 is/are rejected.  
☒ Claim(s) 46-48, 50-57 is/are objected to.  
☒ Claim(s) 46-57 are subject to restriction or election requirements.

#### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

☒ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

**Part III: Detailed Office Action**

**Notice:** Effective June 18, 2000, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1647**.

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Claims 46-57 are pending.

**Species Election Requirement:**

10 Applicant's election with traverse of the species Ab5/12D5 in Paper No. 21, filed 8/6/01 is acknowledged. The traversal is on the ground(s) that the application presents only a single "set" of sequences, which can be searched without undue burden. This is not found persuasive because as stated in the species election requirement, each set of sequence representing an individual antibody species is considered to be distinct because each has a separate and distinct physical structure that requires separate search. Given the exponentially increasing size of the commercial and proprietary  
15 nucleic acid databases, search of more than a single set of nucleic acid sequences is deemed to present an undue burden on the resources of the US Patent and Trademark Office.

The requirement is still deemed proper and is therefore made FINAL.

**Formal Matters:**

20 The claims are objected to for encompassing non-elected species. As the genus has previously been found not to be allowable, examination is now restricted to the elected species only. Applicants are required to cancel all non-elected species from the claims.

25 The use numerous trademarks such as SEPHAROSE, MONO-SEQ ID NO:, etc. (see page 23) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature

of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

**Objections and Rejections under 35 U.S.C. §112:**

5           Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

          The enablement of claim 49 requires availability of the specific antibodies 12D5 claimed therein. This determination has been made because said antibodies are not fully disclosed nor have  
10       they been shown to be publicly known and freely available. Accordingly, it is deemed that a deposit of plasmids containing sequences encoding these antibodies or hybridomas which produced the antibodies should have been made in accordance with MPEP Chapter 2400 and 37 C.F.R. §§1.801-1.809. Applicant is advised that the Patent Office accepts Budapest approved deposits, as long as assurance is provided that the deposited material will be made irrevocably available with no  
15       restrictions upon issuance of a patent. See MPEP Chapter 2400. While this has been done, the statement of deposit at page 57 of the specification is not in compliance with 37 C.F.R. § 1.806, which states:

          A deposit made before or during pendency of an application for patent shall  
20       be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository. In any case, samples must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

25       While the deposit statement at page 57 states that the deposit will be for a term of at least 30 years, it omits to state that the deposit will be maintained for at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository.

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**Prior Art:**

Osbourne et al., U.S. Patent Number 5,872,215 disclose antibody CEA6, which is specific for carcinoembryonic antigen. The V<sub>L</sub> regions of CEA6 are identical to those of applicant's antibody 12D5. However, the V<sub>H</sub> regions are dissimilar.

**Advisory Information:**

No claim is allowed.

Claims 46-48 and 50-57 would be allowable if amended to delete non-elected species from the claims.

Claim 49 would be allowable if the deposit requirement is satisfied and if amended to delete non-elected species from the claim.

Applicant's amendment in paper number 19, filed 5/23/01 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 8:00 A.M. to 4:30 P.M.

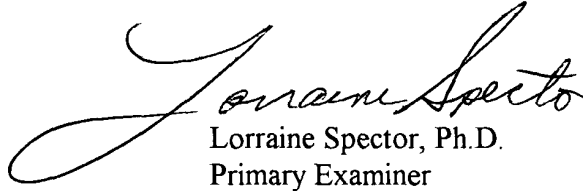
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)

(see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 305-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **Please** advise the Examiner at the telephone number above when an informal fax is being transmitted.

  
Lorraine Spector, Ph.D.  
Primary Examiner

09/138091.3  
10/19/01